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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 17-04911
	)	
S HACKETT MARKETING LLC,	)	
a limited liability company	)	
d/b/a JUST ENHANCE,	)	
R THOMAS MARKETING LLC,	)	

a limited liability company,)
SHAWN HACKETT,)
an individual, and)
ROGER THOMAS,)
an individual,)
)
Defendants.)
_____)

COMPLAINT FOR PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned attorneys, respectfully represents to this Court as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act" or "FDCA"), 21 U.S.C. § 332(a), to permanently enjoin and restrain S Hackett Marketing LLC, a limited liability company doing business as Just Enhance; R Thomas Marketing, a limited liability company; and Shawn Hackett and Roger Thomas, individuals, (collectively, "Defendants") from:

A. violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce new drugs that are neither approved under 21 U.S.C. § 355, nor exempt from approval; and

B. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a).

JURISDICTION AND VENUE

2. This Court has jurisdiction over the subject matter and all parties to this action under 21 U.S.C. § 332(a), 28 U.S.C. §§ 1331, 1337, and 1345, and its inherent equitable authority.

3. Venue in this District is proper under 28 U.S.C. § 1391(b) and (c).

DEFENDANTS

4. Defendant S Hackett Marketing LLC ("S Hackett Marketing") is a limited liability company that primarily operates out of 20 Passaic Street, Trenton, New Jersey, within the jurisdiction of this Court. S Hackett Marketing does business under the name Just Enhance which, in conjunction with the other Defendants, distributes sexual enhancement drugs. S Hackett Marketing has either received drugs at, distributed drugs from, or otherwise associated its business with the following additional addresses: 15A Iron Works Way, Trenton, New Jersey; 439 S. Broad Street, Trenton, New Jersey; 212 Centre Trenton, New Jersey; 407 Wilfred Avenue, Trenton, New Jersey; and 319 Rennie Street, Hamilton, New Jersey, within the jurisdiction of this Court.

5. Defendant Shawn Hackett is the president and owner of Just Enhance. Mr. Hackett engages in receiving and shipping sexual enhancement drugs and managing websites registered to himself, Just Enhance, Roger Thomas, or R Thomas Marketing. Mr. Hackett performs his duties in New Jersey, within the jurisdiction of this Court.

6. Defendant R Thomas Marketing LLC ("R Thomas Marketing") is a limited liability company operating out of its principal place of business at 3704 White Plains Road, Bronx, New York. R Thomas Marketing has either received drugs at, distributed drugs from, or previously operated out of the following addresses: 525 S. 11th Avenue, Mount Vernon, New York; 710 E. 217 Street, Bronx, New York; 3722 White Plains Road, Bronx, New York; and 1023 E. 99th Street, Brooklyn, New York. R Thomas Marketing distributes sexual enhancement drugs to Mr. Hackett in New Jersey, within the jurisdiction of this Court.

7. Defendant Roger Thomas is the president and founder of R Thomas Marketing. Mr. Thomas engages in day-to-day activities such as receiving, packaging, and shipping drugs,

managing and building websites, and assisting customers. He distributes his sexual enhancement drugs to Mr. Hackett in New Jersey, within the jurisdiction of this Court.

8. Defendants work in concert to manage a large network of over one hundred websites, including, but not limited to, africanblackant.org, bullsgenital.com, buddypills.com, herbsviagra.com, and streeoverlordpills.com, to sell their sexual enhancement drugs. Defendants' sexual enhancement drugs include: Africa Black Ant King, African Black Ant, African Superman, Bigger Longer More Time More Sperms, Black Ant, Black Ant King, Black Storm, Bull's Genital, German Black Ant, Germany Niubian, Happy Passenger, Hard Ten Days, Herb Viagra, Jamaican Ants, Lang Yi Hao, Man King, Mojo Risen, Night Man, Plant Vigra, Real Skill, Samurai-X, San Bian Li, Sex Love Secret Code, Stree Overlord, Super Hard, Tiger King, Weekend Prince, Wei Ge Wang, Yi ye Ba Ci Lang, Yong Gang, Zhen Gong Fu, and Zhong Hua Niu Bian.

9. Defendants sell their sexual enhancement drugs in interstate commerce directly to consumers through Defendants' websites and email solicitations.

10. FDA has tested and detected sildenafil in Defendants' African Black Ant, Black Ant, Bull's Genital, Herb Viagra, Real Skill, Stree Overlord, Weekend Prince, and Zhong Hua Niu Bian. Sildenafil is a phosphodiesterase type-5 (PDE-5) inhibitor and the active pharmaceutical ingredient in Viagra, an FDA-approved prescription drug used to treat erectile dysfunction. The use of PDE-5 inhibitors may pose serious health risks to consumers with underlying medical issues, such as heart disease and high blood pressure. Defendants' labeling does not disclose that some of their drugs contain sildenafil, a PDE-5 inhibitor, and thus fails to inform consumers that their use of the drugs could pose serious health risks depending on their underlying medical conditions.

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS

11. A product is a drug within the meaning of the Act if it is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man," 21 U.S.C. § 321(g)(1)(B), or if it is "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C).

12. The intended use of a product may be determined from any relevant source, including the product's labeling. See 21 C.F.R. § 201.128.

13. The Act defines labeling as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m). The Supreme Court has held that the term "accompanying" is not restricted to labels that are on or in the article at issue and that physical attachment to the article is not necessary. See Kordel v. United States, 335 U.S. 345, 349–50 (1948). Rather, labeling includes materials that are textually relevant to the product. See id. at 350. In addition to the labels on Defendants' products, Defendants' labeling includes package inserts that accompany the products and Defendants' websites from which the products may be ordered.

14. Defendants' sexual enhancement products are intended for use to cure, mitigate, treat, and/or prevent various diseases and to affect the structure or any function of the body of man. For example, Defendants' labeling includes disease claims and structure/function claims including the following:

A. Africa Black Ant King: "to prevent early ejaculation"

B. African Black Ant: "Indications: premature ejaculation, impotence, . . . myasthenia of limbs, tinnitus, . . . prostatitis"

C. African Superman: "Has good effect at impotence, premature ejaculation"

D. Bigger Longer More Time More Sperm: "Eliminate premature ejaculation"

E. Black Ant: "Prevent Premature Ejaculation"

F. Black Ant King: "take good therapeutic effect on preventing impotence and premature ejaculation"

G. Black Storm: "completely rescue men from . . . premature ejaculation, impotence"

H. Bull's Genital: "resolve erectile dysfunction"

I. German Black Ant: "prevent the impotence, premature ejaculation"

J. Germany Niubian: "[Applicable group]: ED, premature ejaculation, . . . myasthenia of limbs, . . . prostatitis" (alteration in original)

K. Happy Passenger: "totally rescue males from . . . issues associated with ejaculation problems, male impotence"

L. Hard Ten Days: "Assistant effects on . . . pros[t]atitis and prostatic hyperplasia"

M. Herb Viagra: "Be of good therapeutic effects on prostatitis"

N. Jamaican Ants: "If you are one of those millions of men who remain depressed because of their . . . early ejaculation, there is some good news for you"

O. Lang Yi Hao: "Helps most men with ED maintain an erection during sex"

P. Man King: "Solves impotence and the early ejaculation"

Q. Mojo Risen: "reduces any form of premature ejaculation"

R. Night Man: "Have significant therapeutic effect on prostatitis"

S. Plant Vigra: "Reduces impotence"

T. Real Skill: "with great effect to male's impotence"

U. Samurai-X: "can help cure erectile dysfunction . . . and premature ejaculation"

V. San Bian Li: "do away with renal deficiency"

W. Sex Love Secret Code: "quickly improving impotent, premature ejaculation"

X. Stree Overlord: "Functionality sexual impotence, prostatitis . . . can be used in sexual impotence caused from diabetes"

Y. Super Hard: "applicable to men with . . . prostatitis"

Z. Tiger King: "prevent prostate and other similar diseases"

AA. Weekend Prince: "Weekend Prince Pill will enhance sexual potency in male and female patients"

BB. Wei Ge Wang: "Suitable People: Premature ejaculation"

CC. Yi ye Ba ci Lang: "notice much less problems with premature sexual dysfunction/ejaculation"

DD. Yong Gang: "Suitable People: . . . Career activist man: premature ejaculation, dizziness tinnitus, insomnia"

EE. Zhen Gong Fu: "Functions: . . . solves impotence and the early ejaculation, . . . prostate diseases, . . . mentally depression"

FF. Zhong Hua Niu Bian: "treat rheumatoid arthritis, lumbago/back pain"

15. A "new drug" is defined as any drug "the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions

prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1). For a drug to be "generally recognized as safe and effective" ("GRAS/E"), it must (1) have substantial evidence of safety and effectiveness as demonstrated through adequate and well-controlled clinical studies; (2) the studies on which a claim of GRAS/E is based must be published in the scientific literature so that they are made generally available to the community of qualified experts; and (3) there must be a consensus of opinion among qualified experts, which is based on the published studies, that the drug is safe and effective for its labeled indications. If it is an over-the-counter ("OTC") drug, it must comply with a monograph established under a Food and Drug Administration ("FDA") regulation. 21 U.S.C. § 355(d); 21 C.F.R. § 330.1.

16. A "new drug" may not be introduced or delivered for introduction into interstate commerce unless FDA has approved a new drug application ("NDA") or an abbreviated new drug application ("ANDA") with respect to such drug, or such drug is exempt from approval under an investigational new drug application ("IND"). 21 U.S.C. § 355(a), (b), (j), and (i).

17. The introduction or delivery for introduction into interstate commerce of an unapproved new drug violates the Act. 21 U.S.C. § 331(d).

18. FDA searched the literature and found no adequate and well-controlled studies demonstrating substantial evidence of safety and effectiveness for any of Defendants' sexual enhancement products. Therefore, Defendants' sexual enhancement drugs are "new drugs," because they are drugs within the meaning of 21 U.S.C. § 321(p) and they are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in their labeling. Moreover, Defendants' sexual enhancement drugs do not conform to any OTC drug monograph.

19. FDA representatives searched agency records and determined that Defendants do not have an approved NDA or ANDA or an effective IND for any of their drugs.

20. Defendants introduce or deliver for introduction, or cause the introduction or delivery for introduction, into interstate commerce of unapproved new drugs in violation of 21 U.S.C. § 331(d).

DEFENDANTS DISTRIBUTE MISBRANDED DRUGS

21. The introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce, of misbranded drugs violates the Act. 21 U.S.C. § 331(a).

22. A drug is misbranded within the meaning of 21 U.S.C. § 352(f)(1) if its labeling fails to bear "adequate directions for use" and does not fall within a regulatory exemption to this requirement. 21 C.F.R. § 201.5. Under 21 C.F.R. § 201.5, "adequate directions for use" are defined as "directions under which the layman can use a drug safely and for the purpose for which it is intended."

23. Because Defendants' drugs are unapproved new drugs, as described above, they are not exempt from the requirement for adequate directions for use. See 21 C.F.R. §§ 201.100(c)(2), 201.115.

24. By definition, a drug that is also a prescription drug cannot have adequate instructions for lay use. 21 U.S.C. § 353(b)(1)(A)(requiring a drug to be dispensed by prescription that, "because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug").

25. Because of the toxicity or other potentiality for harmful effect associated with the presence of sildenafil, Defendants' sildenafil-containing drugs, including African Black Ant, Black Ant, Bull's Genital, Herb Viagra, Real Skill, Stree Overlord, Weekend Prince, and Zhong Hua Niu Bian, are prescription drugs. Additionally, all of Defendants' drugs are prescription drugs because medical expertise and special clinical assessments are needed to diagnose and determine appropriate therapeutic interventions for many of their intended uses, including erectile dysfunction, impotence, and prostatitis. As a matter of law, "adequate directions for use" cannot be written for Defendants' drugs. See 21 U.S.C. § 352(f)(1); 21 C.F.R. § 201.5. And, as mentioned above, Defendants' drugs are not exempt from the requirement for adequate directions for use. See 21 C.F.R. § 201.100.

26. Moreover, adequate directions for use must be based on animal and clinical data derived from extensive, scientifically controlled testing. It would be impossible to write such directions for Defendants' drugs, because adequate directions for drug use, including indications, contraindications, dosages, routes of administration, warnings, side effects, and necessary collateral measures, are necessarily premised on animal and clinical data derived from extensive, scientifically controlled testing, which Defendants' products do not have.

27. Defendants' drugs are misbranded drugs within the meaning of 21 U.S.C. § 352(f)(1), because they fail to bear adequate directions for use.

28. A drug is also misbranded if its "labeling is false or misleading in any particular." 21 U.S.C. § 352(a). The Act provides that, "in determining whether the labeling . . . is misleading there shall be taken into account . . . not only representations made or suggested . . . but also the extent to which the labeling . . . fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the

article to which the labeling . . . relates under the conditions of use prescribed in the labeling." 21 U.S.C. § 321(n).

29. The labeling for Defendants' sildenafil-containing drugs is false and misleading because it does not declare that the drugs contain sildenafil or reveal the consequences that may result from using a drug containing sildenafil. Thus, these drugs are also misbranded within the meaning of 21 U.S.C. § 352(a).

30. Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing the introduction or delivery for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a).

DEFENDANTS DISTRIBUTE UNAPPROVED NEW DRUGS AND MISBRANDED DRUGS IN INTERSTATE COMMERCE

31. During a January 2016 inspection at R Thomas Marketing, Mr. Thomas told FDA investigators that Defendants distribute their sexual enhancement drugs to customers across the United States. In July 2016, Just Enhance mailed African Black Ant, Black Ant, Herb Viagra, and Real Skill from New Jersey to Maryland. Additionally, in September 2016, R Thomas Marketing shipped African Black Ant and Real Skill from New York to Maryland. These shipments constitute the introduction or delivery for introduction, or causing the introduction or delivery for introduction, into interstate commerce of unapproved new drugs and misbranded drugs in violation of 21 U.S.C. § 331(a) and (d).

HISTORY

32. Defendants are aware that their conduct violates the law and that continued violations could lead to regulatory action.

33. In January and March 2015, FDA made several undercover purchases of sexual enhancement drugs from Defendants' websites, including Black Ant (from herbsviagra.com),

Herb Viagra (from herbsviagra.com and herbviagra.com), Real Skill (from herbsviagra.com), and Stree Overlord (from herbsviagra.com). Following these purchases, on July 31, 2015, FDA issued a Warning Letter to Defendants, notifying them that they were distributing unapproved new drugs and misbranded drugs in violation of the Act and its regulations. FDA also warned Defendants that the violations noted in the Warning Letter were not an all-inclusive list of violations and reminded Defendants that it was their responsibility to ensure that all of the products that they distribute comply with the law.

34. Defendants did not respond to the Warning Letter. In December 2015, FDA made several undercover purchases of sexual enhancement drugs from Defendants' websites, including Bull (from bullsexpills.com), Bull's Genital (from bullsgenital.com), Herb Viagra (from herbsviagra.com), Real Skill (from buddypills.com), and Zhong Hua Niu Bian (from zhonghuaniubian.org).

35. In January 2016, Defendants agreed to voluntarily recall the following sexual enhancement drugs: African Black Ant, African Superman, Bigger Longer More Time More Sperms, Black Ant, Black Ant King, Black Storm, Bull, Bull's Genital, Germany Niubian, Happy Passengers, Hard Ten Days, Herb Viagra, Man King, Mojo Risen, Night Man, Plant Vigra, Real Skill, Samurai-X, Stree Overlord, Superhard, Tiger King, Weekend Prince, Zhen Gong Fu, and Zhong Hua Niu Bian. Mr. Thomas told FDA that all recalled product would be shipped to Mr. Hackett in New Jersey.

36. Also in January 2016, FDA investigators conducted an inspection at 3704 White Plains Road, Bronx, New York, the business address of R Thomas Marketing. During the January 2016 inspection, Mr. Thomas told investigators that he would no longer distribute sexual enhancement drugs and was going to concentrate on distributing other items, such as adult sex

toys, hair extensions, and hover boards. While the inspection was ongoing, FDA was able to complete an undercover purchase of Black Ant and Herb Viagra from one of Defendants' websites (streeoverlordpills.com).

37. In February 2016, through a consulting firm acting on behalf of Defendants, Defendants told FDA that they had terminated fifty-seven of their websites from which they offered their drugs for sale. Defendants said that eight of their websites would remain active temporarily with the recall notice posted.

38. In June 2016, through a consulting firm acting on behalf of Defendants, Defendants informed FDA that they had not distributed any of their drugs since November 2015.

39. In July 2016, FDA made undercover purchases from Defendants of African Black Ant (from africanblackant.org), Black Ant (from blackantpills.us), Herb Viagra (from blackantpills.us), and Real Skill (from blackantpills.us).

40. During an August 2016 phone call with FDA, Mr. Thomas and Mr. Hackett again claimed that they had not distributed sexual enhancement drugs since November 2015.

41. In September 2016, R Thomas Marketing sent a solicitation email to an FDA undercover account and FDA purchased African Black Ant and Real Skill. The drugs shipped to FDA from R Thomas Marketing's business address in New York. Mr. Hackett and Just Enhance also sent a solicitation email to an FDA undercover account in September 2016, which included a link to purchase sexual enhancement drugs on a website registered to Mr. Thomas.

42. In December 2016, Mr. Hackett and Just Enhance sent to an FDA undercover account a solicitation email with the subject line "Male Enhancement Holiday sale!!!." In response to this email solicitation, FDA made an undercover purchase of African Black Ant from africanblackant.org, which shipped to FDA from Hamilton, New Jersey. Also, in December

2016, in response to a solicitation email from R Thomas Marketing, FDA made undercover purchases of African Black Ant and Herb Viagra from rthomasmarketingbiz@gmail.com via the RTM Biz/rogerthomas102030@gmail.com PayPal account. Mr. Thomas shipped these drugs to FDA from Bronx, New York.

43. Despite FDA's multiple warnings and Defendants' promises to cease the distribution of unapproved and misbranded drugs, Defendants refuse to comply with the law. Based on Defendants' conduct, it is evident that, unless restrained by order of this Court, Defendants will continue to violate the Act, 21 U.S.C. § 331(a) and (d).

WHEREFORE, the United States respectfully requests that the Court:

I. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from doing or causing to be done any of the following acts:

A. violating 21 U.S.C. § 331(d) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce unapproved new drugs;

B. violating 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(f)(1) and (a);

II. Permanently restrain and enjoin, under 21 U.S.C. § 332(a), Defendants, and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly introducing or delivering for introduction, or causing to be introduced or delivered

for introduction, into interstate commerce any sexual enhancement drugs, all formulations of those products, and the same or similar products designated by any other name, and any new drug, unless and until an approved new drug application, an abbreviated new drug application, or an investigational new drug application filed pursuant to 21 U.S.C. § 355(a), (b), (j), or (i) is in effect for such drugs.

III. Order that Defendants destroy, under FDA's supervision and at Defendants' expense, all sexual enhancement drugs, any product labeled similarly to such products, and any new drug in their custody, control, or possession, and that the costs of FDA's supervision be borne by Defendants at the rates prevailing at the time the destruction is accomplished.

IV. Order that FDA be authorized to inspect all locations where Defendants operate and all records relating to receipt, holding, and distributing of any of Defendants' products to ensure continuing compliance with the terms of the injunction, the costs of such inspections to be borne by Defendants at the rates prevailing at the time the inspections are accomplished.

V. Order that Plaintiff be granted judgment for its costs herein, and that this Court grant such other and further relief as it deems just and proper.

DATED: July 5, 2017

Respectfully submitted,

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